



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 23, 2016

Amy Plato Roberts
Authorized Agent for Botry-Zen (2010) Limited
c/o Technology Sciences Group, Inc.
1150 18th Street NW, Suite 1000
Washington, DC 20036

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation
Amendment – To correct the viability statement on the label and basic Confidential
Statement of Formula (CSF) and make other revisions to the label and CSF requested by
the EPA
Product Name: BOTRY-Zen®
EPA Registration Number: 75747-2
Application Date: September 6, 2016
OPP Decision Number: 521807

Dear Ms. Roberts:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 12/22/2016

Any CSFs other than those listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling

or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact me by phone at (703) 347-8920 or via email at kausch.jeannine@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeannine Kausch', with a stylized flourish at the end.

Jeannine Kausch, Acting Product Manager 92
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

BOTRY-Zen®

(Alternate Brand Names: "Zen-O-Spore"; "Zen-O-Spore Biofungicide")

ACTIVE INGREDIENT:

Ulocladium oudemansii (U3 Strain)* 45.00%

OTHER INGREDIENTS: 55.00%

TOTAL: 100.00%

*Contains not less than 8×10^7 cfu/gram of BOTRY-Zen®.

KEEP OUT OF REACH OF CHILDREN CAUTION

FIRST AID	
If inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.	

See (back) (side) panel for additional precautionary statements and directions for use.

EPA Reg. No.: 75747-2

Net Weight: 9 lbs (4 kg) or 12 lbs (5.4 kg)

EPA Establishment No.: XXXXX-XX-XX

(Use By: (date 11 months from date of manufacture))

(Batch No. / Lot No.: XXX)

Manufactured by:

Botry-Zen (2010) Limited
156 Frederick Street, PO Box 1777
Dunedin 9054
New Zealand
www.botryzen.co.nz

Distributed by:

(U.S. name and address –to be determined)

ACCEPTED

12/23/2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 75747-2

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals - CAUTION. Harmful if inhaled. Causes moderate eye irritation. Avoid contact with eyes or clothing. Avoid breathing dust or spray mist. Wear safety glasses or goggles. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE): Applicators and other handlers must wear long-sleeved shirt and long pants, waterproof gloves, and shoes plus socks. Mixer/loaders and applicators, not in enclosed cabs, must wear a NIOSH approved particulate respirator with any R or P filter with NIOSH approval number prefix TC-84A; or a NIOSH approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning / maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations: Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards: For terrestrial uses: Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean highwater mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on the label about personal protective equipment (PPE), and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water is: coveralls, waterproof gloves, shoes plus socks.

Use Restrictions:

Do not apply this product through any type of irrigation system.

Product Information: BOTRY-Zen® is a biological control agent developed specifically for the control of *Botrytis cinerea*, *Sclerotinia sclerotiorum* and other organisms listed in the Application Rates section in this label.

BOTRY-Zen® is a live spore preparation of a non-pathogenic saprophytic fungus. BOTRY-Zen® acts as a biological control agent by competing for the same ecological niche as the plant pathogens *Botrytis cinerea*, *Sclerotinia sclerotiorum* and other organisms listed in the Application Rates section.

When BOTRY-Zen® spores are deposited on the dead and senescent plant debris they germinate and colonize. The developed mycelium will proceed to colonize the dead tissue and additional sporulation can occur and these new spores are then available to colonize remaining debris. Apply BOTRY-Zen® when conditions are conducive to the development of disease, specifically warm temperatures (60 - 70°F) and a moist or humid environment. Disease typically develops during flowering and under warm and moist or humid conditions.

BOTRY-Zen® aggressively occupies the same physical space and out competes *Botrytis* spp., *Sclerotinia* spp., and other organisms listed in the Application Rates section for the nutrients in the dead and senescing plant tissue; it is a true antagonist. BOTRY-Zen® is non-invasive and causes no damage to live plant tissue. With this mechanism of action, it is highly unlikely that resistance to BOTRY-Zen® will develop.

(Integrated Pest Management: Integrating BOTRY-Zen® into an overall pest management strategy and following best management practices (or practices known to reduce disease development) makes it less likely that disease will be established. Specific IPM strategies developed for your crop and location may be available from the Extension Service or other local agricultural authorities.)

Mixing and Application Instructions:

MIXING: Dilute BOTRY-Zen® with water and apply in conventional spray equipment. Partially fill the spray tank with clean water and begin agitation. Add the specified amount of BOTRY-Zen® to the tank. Finish filling the tank to the desired volume to obtain the proper spray concentration. Add a surfactant or a non-ionic adjuvant to improve product wetting / spreading. Maintain agitation continuously while spraying. Use spray mixture immediately. Do not allow spray mixture to stand overnight or for prolonged periods.

APPLICATION: Apply BOTRY-Zen® using conventional spray equipment to the point of saturation. Good coverage and wetting is required. The amount of spray solution to apply will vary depending on the type of crop. Most row crops will require up to 100 gallons of spray per acre. Apply in sufficient water to achieve thorough coverage.

COMPATIBILITY: BOTRY-Zen® may be tank mixed with some fungicides. Do not tank mix BOTRY-Zen® with more than one product. Consult specific product labels for additional information or restrictions concerning tank mixing. Observe the most restrictive of the labeling limitations and precautions of all products used in mixtures. It is always advisable to conduct a spray compatibility test when you plan to mix this product with another product. To determine the physical compatibility of this product with other products, use a jar test. Using a quart jar, add the proportionate amounts of the products to approximately one quart of water with agitation. Add dry formulations first, then flowables, and then emulsifiable concentrates last. After thorough mixing, allow this mixture to stand for 5 minutes. If the combination remains mixed or can be readily remixed, it is physically compatible. Once compatibility has been proven, use the same procedure for adding products to the spray tank.

BOTRY-Zen® has been evaluated for phytotoxicity on a variety of crops under various normal growing conditions. However, testing all crop varieties, in all mixtures and combinations is not feasible. Prior to treating entire crop, test a small portion of the crop for sensitivity.

Application Rates:

Crops	Disease	Lbs Product /Acre	Notes
Asparagus	Botrytis Blight	2 - 4	Begin application soon after emergence and when conditions are conducive to disease development*. Repeat on 7 to 10 day intervals or as needed.
Berries and Small Fruits, including (except for Grapes, Kiwifruit and Strawberry): Blackberry Blueberry Bushberry Caneberry Cranberry Currants Elderberry Gooseberry Huckleberry Loganberry Raspberry	Botrytis Blight Mummy Berry <i>(Monilinia vaccinii-corymbosi)</i>	2 - 4	Apply during early bloom and repeat on a 7 to 10 day interval or as needed.
Bulb Vegetables, including: Garlic Leeks Onions Shallots	Botrytis Leaf Blight Botrytis Neck Rot <i>Botrytis squamosa</i> <i>Botrytis</i> spp.	2 - 4	Begin application when conditions are conducive to disease development*. Repeat on 7 to 10 day intervals or as needed.
Citrus Fruits, including: Calamondin Citrus citron Citrus hybrids Grapefruit Kumquat Lemon Lime Mandarin Orange, sour and sweet Pummelo Satsuma mandarin	<i>Botrytis cinerea</i>	2 - 4	Begin application when conditions are conducive to disease development*. Repeat on 7 to 10 day intervals or as needed.
Cucurbit Vegetables, including:	Gray Mold (<i>Botrytis cinerea</i>)	2 - 4	Begin application when conditions are conducive to disease development*. Repeat on 7 to 10 day intervals or as needed.

Cucumbers Melons Squash Zucchini			
Fruiting Vegetables, including: Eggplant Okra Pepper Tomato Tomatillo	Gray Mold (<i>Botrytis cinerea</i>)	2 - 4	Begin application when conditions are conducive to disease development*. Repeat on 7 to 10 day intervals or as needed.
Grapes	Gray Mold (<i>Botrytis cinerea</i>)	2 - 4	Apply at early and late bloom, then again when the berries are pea-sized, and finally at pre-bunch closure. Spray onto vines ensuring the bunch zone is well covered.
Kiwifruit	Gray Mold (<i>Botrytis cinerea</i>) <i>Sclerotinia sclerotiorum</i>	2 - 4	Make applications at 30% and 80% flowering. Do not apply after the bloom period.
Leafy Vegetables, including: Broccoli Cabbage Celery Collards Lettuce Spinach	Sclerotinia Head and Leaf Drop <i>Sclerotinia</i> spp. <i>Botrytis cinerea</i>	2 - 4	Begin application when conditions are conducive to disease development*. Repeat on 7 to 10 day intervals or as needed.
Legumes, succulent and dried, including: Field beans Lentils Peas Peanuts Soybeans	<i>Sclerotinia sclerotiorum</i> Sclerotinia Stem Rot	2 - 4	Begin application when conditions are conducive to disease development*. Repeat on 7 to 10 day intervals or as needed.
Ornamental Plants Bedding Plants	Gray Mold (<i>Botrytis cinerea</i>)	2 - 4	Ornamentals grown in nurseries and greenhouses. Begin application when conditions are conducive to disease development*. Repeat on 7 to 10 day intervals or as needed.
Passionfruit	Gray Mold (<i>Botrytis cinerea</i>) <i>Sclerotinia sclerotiorum</i>	2 - 4	Begin application when conditions are conducive to disease development*. Repeat on 7 to 10 day intervals or as needed.

Pome Fruits, including: Apple Crabapple Loquat Mayhaw Pear Pear, oriental Quince	<i>Erwinia amylovora</i>	2 - 4	Apply at early and late bloom. For extended bloom periods, apply on a 7 – 10 day interval.
Root, Tuber and Corm Vegetables, including: Beets Carrots Cassava Ginger Potato Radish Sugar beets Sweet potato Yams	Gray Mold (<i>Botrytis cinerea</i>) <i>Sclerotinia sclerotiorum</i>	2 - 4	Begin application when conditions are conducive to disease development*. Repeat on 7 to 10 day intervals or as needed.
Stone Fruits, including: Apricot Cherry, sweet and tart Nectarine Peach Plum Plumcot Prune (fresh)	Brown Rot Blossom Blight (<i>Monilinia</i> spp.) Jacket Rot, Green Fruit Rot (<i>Botrytis cinerea</i> , <i>Monilinia</i> spp., <i>Sclerotinia sclerotiorum</i>)	2 - 4	Apply at early and late bloom. For extended bloom periods, apply on a 7 – 10 day interval.
Tree nuts, including: Almond Beech nut Brazil nut Butternut Cashew Chestnut Chinquapin Filbert (hazelnut) Hickory nut Macadamia nut Pecan Walnut, Black and English	Brown Rot Blossom Blight (<i>Monilinia</i> spp.) Jacket Rot, Green Fruit Rot (<i>Botrytis cinerea</i> , <i>Monilinia</i> spp., <i>Sclerotinia sclerotiorum</i>)	2 - 4	Apply at early and late bloom. For extended bloom periods, apply on a 7 – 10 day interval.
Strawberries	Gray Mold (<i>Botrytis cinerea</i>)	2 - 4	Begin application at or before flowering. Repeat on 7 to 10 day intervals or as needed up until harvest.

* See **Product Information** section for description of when conditions are conducive to disease development.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry place at or below 68°F (20°C). Store in original container only. Keep container tightly closed when not in use.

Pesticide Disposal: Wastes resulting from use of this product must be disposed of on site or at an approved waste disposal facility.


Container Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration. Do not burn, unless allowed by state and local ordinances. If burned, stay out of smoke.

WARRANTY STATEMENT

Botry-Zen (2010) Limited warrants that this product conforms to its description and is reasonably fit for the purposes stated on this label when used in accordance with Seller's directions. Buyers and users of this product assume the risk of any use contrary to such directions. SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTEE, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO. To the extent consistent with applicable law, the Seller's liability for any breach of warranty shall not exceed the purchase price of the material as to which a claim is made.

To the extent consistent with applicable law, Buyers and users of this product are responsible for all loss or damage from use or handling of this product which results from conditions beyond the control of Seller, or without the fault or negligence of the Seller.

OPTIONAL LABEL CLAIMS

- Biofungicide.
-  (For Organic Production) (For Use in Organic Production)
- OMRI-Listed (logo)
- Biological control of (*Botrytis cinerea*) (*Sclerotinia sclerotiorum*) (*Monilinia* spp.).
- The Biological Solution for *Botrytis cinerea* and *Sclerotinia sclerotiorum* and *Monilinia* spp.
- 4 Hour Reentry Interval (REI).